

REMARKS

Claims 123-127, 141, 142 and 149-158 were pending in the present application. By virtue of this response, claims 124-125, 127, and 142 have been canceled, claims 123, 126, 141, and 149-158 have been amended, and new claims 159-160 have been added. Accordingly, claims 123, 126, 141, and 149-160 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added.

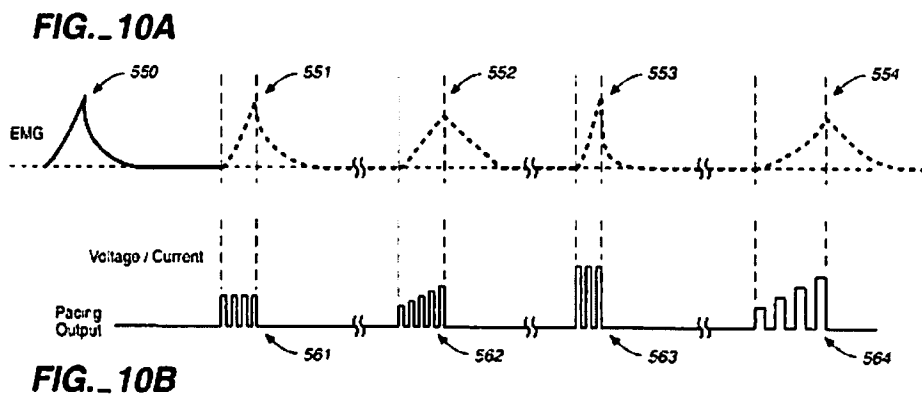
Rejections under 35 U.S.C. §103

Claims 123-127, 141, 142 and 149-158 are rejected in the alternative under 35 U.S.C. §103(a) as obvious over Scheiner et al. (US 6,415,183) in view of Meer (US 4,830,008).

Independent claim 123 has been amended to recite “wherein said stimulator is configured to deliver an electrical stimulation signal comprising a burst or series of pulses during inspiration to adjust the breathing cycle of said patient”. Claim 123 has been further amended to recite “wherein the electrical stimulation signal is configured to elicit a diaphragm response by stimulating to increase an inspiration duration which supplements a breath.”

Independent claim 126 has been similarly amended to claim 123 above and has also been amended to recite “wherein the electrical stimulation signal is configured to elicit a diaphragm response by stimulating to supplement an inspiration volume of a breath.”

As described, the device “may be programmed to provide certain stimulation parameters such as pulse or burst morphology” where the electrical stimulation may be applied as a burst or series of pulses having a distinct amplitude, frequency, and pulse width. Support may be found throughout the specification, e.g., at [0054].



As further shown and described in the specification at Fig. 10B (shown above), examples are illustrated to show, in one example, how an EMG waveform 550 (indicative of each breath during respiration) responds to an applied burst of pulses 562 to control various parameters of the breath. (Specification, [0058].)

Scheiner et al., on the other hand, shows and describes pulses applied to heart tissue which cannot be described as being a burst or series of pulses applied as the electrical stimulation. Rather, the pulses of Scheiner et al. are described as having a conventional waveform consistent with those typically delivered by, e.g., a defibrillator. (Scheiner et al., 8: 53-56.)

Furthermore, support may be found for the electrical stimulation signal being configured to elicit a diaphragm response by stimulating to increase an inspiration duration which supplements a breath. As described, “[t]he system may adjust the pace, pulse, frequency and amplitude to induce slow and elongated inspiration period” The specification continues where “[t]his may be done gradually by frequently sensing and incrementally adjusting. The system may deliver elongated inspiration period while shortening the expiration period to control and manipulate PO_2 and PCO_2 levels in the blood to overcome and treat apnea.... To increase the inspiration period, the system may deliver fewer bursts at lower amplitudes and higher frequencies.” (Specification, [0057].)

Neither Scheiner et al. nor Meer teach or describe delivering an electrical stimulation signal which is configured to elicit a diaphragm response by stimulating to supplement an inspiration volume of a breath.

Independent claim 153 has been amended similarly to claim 123 above and has been further amended to recite “wherein the electrical stimulation signal is configured to activate

at least a portion of the diaphragm and to further control or manage pulmonary stretch receptors to maintain airway patency.” As described, “[t]he system may deliver sequential low energy pacing output either from one or multiple electrodes to control and manage the pulmonary stretch receptor threshold levels to avoid or prevent collapse of the upper airways.” (Specification, [0057].)

As known in the art, pulmonary stretch receptors are mechanoreceptors found in the lungs and the presently claimed invention may be used to deliver the electrical stimulation signal to control or manage these pulmonary stretch receptors to maintain airway patency. Scheiner et al. fails to teach or describe such application of an electrical stimulation and Meer may teach the maintenance of the upper airway but similarly fails to teach or describe such an application of stimulation. Rather Meer teaches the activation of upper airway muscles where “an electrical signal is generated as necessary at the appropriate instant during the respiratory cycle to activate those muscles that move the patient’s tongue anteriorly and maintain upper airway patency” instead of controlling or managing the pulmonary stretch receptors to maintain airway patency. (See Meer, 2: 38-39 & 45-49.)

Neither Scheiner et al. nor Meer teach or describe delivering an electrical stimulation signal which is configured to activate at least a portion of the diaphragm and to further control or manage pulmonary stretch receptors to maintain airway patency.

Hence, Scheiner et al. fails to teach or describe a device which is programmed to deliver a burst or series of pulses as the electrical stimulation. Meer further fails to cure the defects of Scheiner et al. Moreover, neither Scheiner et al. nor Meer teach or describe an electrical stimulation signal which is configured to elicit a diaphragm response by stimulating to increase an inspiration duration which supplements a breath, stimulating to supplement an inspiration volume of a breath, or an electrical stimulation signal which is configured to activate at least a portion of the diaphragm and to further control or manage pulmonary stretch receptors to maintain airway patency.

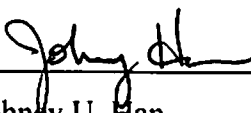
Thus each of the independent claims is patentable over Scheiner et al. and Meer either alone or in combination and the dependent claims are patentable for at least the same reasons. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **RMXLNZ00100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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